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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,245	06/07/2005	David Feifel	00015-067US1/SD2003-090-1	3580

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Joseph R. Baker, APC
Gavrilovich, Dodd & Lindsey LLP
4660 La Jolla Village Drive, Suite 750
San Diego, CA 92122

EXAMINER	
DUTT, ADITI	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
01/28/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,245	FEIFEL, DAVID	
	Examiner	Art Unit	
	Aditi Dutt	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-18,22 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-18,22 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicant's amendments filed 4 December 2009 have been entered. The final rejection mailed 6 July 2009 has been withdrawn. Prosecution is hereby re-opened. Claims 15, 16 and 24 have been amended.

2. All other rejections and/or objections are withdrawn in view of Applicant's arguments and amendments filed 4 December 2009. Applicant's arguments and submission of articles teaching models for depression and anxiety are found to be persuasive.

Priority

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See Transco Products, Inc. v. Performance Contracting, Inc., 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994) (emphasis added).

4. In the instant case, the invention of claims 15-18, 22, 24-26, directed to a

method of inhibiting serotonin-2A and/or alpha-1 receptor mediated neural function by administration of NT69L to a subject, does not appear in the provisional application 60/431937, filed 9 December 2002. Support for such appears in the International application PCT/US03/39196, filed 8 December 2003; therefore claims 15-18, 22, 24-26 will be given the priority date of 8 December 2003.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 15-16, 18, 22, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shilling et al. (Behav Brain Res 143: 7-14, July 2003), in view of Perry et al. (Biol Psychiat 50: 418-424, 2001).

6. The claims are drawn to a method for increasing sensorimotor gating or inhibiting serotonin-2A and/or alpha-1 receptor mediated neural function in a subject having a bipolar disease, anxiety disease or depression, comprising the administration of NT69L, alone or in combination with other psychotropic drugs, to improve symptoms of the disorder (claims 15-16, 22, 24). The claims further

recite the administration of NT69L via various routes such as parenteral, topical, subcutaneous, etc. (claims 18 and 26).

7. Shilling et al teach that a subcutaneous (s.c.) injection of NT69L in rats increases the prepulse inhibition PPI in saline treated and in rats treated with antipsychotic drugs - NMDA antagonist dizocilpine and amphetamine (Materials and methods, Section 2.2; Figure 1, Figure 3). Shilling et al further teach that the effect of NT69L in antagonizing the PPI deficit could occur by interfering with neurotransmission at serotonin-2A (5HT2A) or alpha-1 adrenergic receptors (abstract; page 12, col 1, para 6).

8. Shilling et al. do not teach the association of PPI with sensorimotor gating or diseases/disorders consisting of bipolar, depression or anxiety in humans.

9. Perry et al. teach that sensorimotor gating deficits as assessed by significantly lower PPI and habituation of the human startle response is observed in bipolar disorder patients (Abstract).

10. It would have been obvious to the person of ordinary skill in the art at the time the claimed invention was made to modify the use of NT69L for increasing baseline PPI in normal rats or reversing dizocilpine or amphetamine induced decreased PPI in view of Shilling et al. by administering NT69L to a bipolar disorder human subject to increase PPI and thereby increase sensorimotor gating in view of Perry et al. The person of ordinary skill in the art would have been motivated to use NT69L in bipolar disorder human subjects because the reversal of non-dopaminergic agent induced PPI deficit and baseline PPI by

NT69L proves that this is an atypical antipsychotic drug that can be further evaluated for preclinical studies (Shilling et al. page 11, col 2, para 3). The person of ordinary skill in the art would have expected success because the use of antipsychotics in the facilitation of baseline PPI was known in the art at the time the invention was made.

11. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

12. Claims 15-17, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shilling et al. (Behav Brain Res 143: 7-14, July 2003), and Perry et al. (Biol Psychiat 50: 418-424, 2001), in view of Gully et al (Therapie 50: 5-7, 1995 - abstract) and Greibel et al. (Neurosc Behav Rev 25: 619-626, 2001).

13. Claims 17 and 25 further teach the administration of a compound selected from the group consisting of levocobastine, SR48692 and SR142948.

14. The teachings of Shilling et al. and Perry et al. are set forth above.

15. Shilling et al. or Perry et al. do not teach further administration of a compound selected from levocabastine, SR48692 and SR142948.

16. Gully et al teach that following administration in vivo, the non-peptide neurotensin receptor antagonist SR48692 crosses the blood-brain barrier, modulates central dopaminergic neurons and can be involved in the pathophysiology of psychiatric diseases (abstract).

17. Griebel et al teach that intraperitoneal administration of NT1 receptor antagonist SR48692 in rodent models results in effectively treating generalized anxiety disorders (Figure 4; abstract; page 624, col 2, para 2). It is well established that anxiety disorders have prepulse inhibition deficits of the acoustic startle response, thereby showing decreased sensorimotor gating.

18. Neither the combination of Shilling et al. and Perry et al., nor the combination of Gully et al. and Griebel et al. teach a process for increasing sensorimotor gating in a subject having the claimed disorders by administration of NT69L or NT69L plus psychotropic drug (e.g. dizocilpine, amphetamine, etc.) and another compound, e.g. SR48692. However, in the absence of unexpected results, it would have been *prima facie* obvious to one of ordinary skill in the art to combine the teachings of the references and to administer NT69L or NT69L plus amphetamine along with SR48692. Each of the compounds, NT69L and the NT receptor antagonist SR48692 had been taught by the prior art to reduce or inhibit amphetamine induced behavior and thus behave as antipsychotic compounds. The instant situation is amenable to the type of analysis set forth in In re Kerkhoven,205 USPQ 1069 (CCPA 1980) wherein the court held that it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to for a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant process claims, given the teaching of the prior art of

processes using the administration of NT69L or SR48692 individually for increasing sensorimotor gating in psychiatric disorders like bipolar disorder or anxiety, thereby implicating an usefulness in neuropsychiatric conditions, it would have been obvious to administer to a subject both NT69L and SR489692, because the idea of doing so would have logically followed from their having been individually taught in the prior art to be useful as antipsychotic compounds for the same purpose of in neuropsychiatric diseases, for example as in the claimed invention. One of ordinary skill in the art would have reasonably expected to obtain the claimed effect of increasing sensorimotor gating upon administration of either or both of these neurotensinergic compounds since both had been implicated for clinical usefulness in neuropsychiatric disorders in the prior art.

19. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

20. No claims are allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571) 272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on (571) 272-0911. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov/. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

14 December 2010
AD

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649